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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/822,904	04/12/2004	Paul A. Rota	6395-67788-01	7102

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EXAMINER	
MOSHER, MARY	
ART UNIT	**PAPER NUMBER**
1648	

DATE MAILED: 04/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/822,904	ROTA ET AL.	
	Examiner	Art Unit	
	Mary E. Mosher, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-23 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-23 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claim 1, drawn to SARS full genomic nucleic acid (SEQ 1), classified in class 536, subclass 23.72, and 435/235.1.

II. Claim 2, drawn to isolated virus polypeptide, classified in class 435, subclass 235.1 and 530/350. If this group is elected, election of species is further required.

III. Claims 3-4, drawn to isolated nucleic acid encoding viral polypeptide, classified in class 536, subclass 23.72 and 435/320.1. If this group is elected, election of species is further required.

IV. Claims 5-10, 15-18, drawn to detection method using nucleic acid amplification, primers & probes, classified in class 435, subclass 5 and 536/24.32, 24.33. If this group is elected, election of species is further required.

V. Claims 11, 19-23, drawn to isolated virus, compositions and immunoassay using virus, classified in class 424, subclass 204.1 and 435/235.1.

VI. Claims 12-14, drawn to detection method using antibodies, classified in class 435, subclass 5 and 7.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions I, III, and IV are related as a nucleic acid combination (SEQ 1) and subcombinations (SEQ 13-33 and sequences encoding SEQ 2-12). Inventions in this

relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed (SEQ 1) does not require the particulars of any specific subcombination for patentability as claimed because it can rely upon the sequence of any other part of SEQ 1 for patentability. Each subcombination has separate utility such as a PCR primer or as a recombinant expression unit.

Although there are no provisions under the section for "Relationship of Inventions" in MPEP §806.05 for inventive groups that are directed to different products, restriction is deemed to be proper because the products of groups I, II, III, and V constitute apparently distinct inventions for the following reasons:

The nucleic acids of groups I and III, the isolated proteins of group II, and the intact virus of group V, are structurally, functionally, and chemically distinct products. The products of groups I, II, and III can be independently synthesized by chemical means, and the virus of group V can be produced independent of the isolated products of groups I-III by isolation from infected material or by serial propagation on cultured cells. Each product has a separate utility capable of use independent of the others.

The diagnostic methods of groups IV-VI are mutually unrelated, because each method uses materially different starting materials and materially different active steps, to detect materially different products (detecting nucleic acid, antibodies, and antigens, respectively).

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their different classification, divergent search requirements, and recognized divergent subject matter, restriction for examination purposes as indicated is proper.

In groups II and III, the claims are generic to a plurality of disclosed patentably distinct species of protein or nucleic acid involving SEQs 2-12. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed. The species are distinct, because each involves a different protein with different functional properties, without a common structure.

In group IV, the claims are generic to a plurality of disclosed patentably distinct species of primer and/or probe comprising SEQ 13-33. Applicant is required under 35 U.S.C. 121 to elect a single primer or probe, or a set of paired of primers and a probe, even though this requirement is traversed. The species are distinct, because each oligonucleotide is distinct in structure from the others, and hybridizes to a different segment of the SARS genome.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over

the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. Mosher, Ph.D. whose telephone number is 571-272-0906. The examiner can normally be reached on M-T and alternate F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

3/31/05

MARY E. MOSHER, PH.D.
PRIMARY EXAMINER